

## **Introduction**

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

### **Definition of Terms:**

Allograft – transplant from one individual to another (synonymous with homograft)

Hereotopic graft – transplant placed in a site different than the organ's normal location

Orthotopic graft – transplant placed in its normal anatomical site

Syngeneic graft (isograft) – transplant between identical twins

Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

## **1.0 Definition of the Procedure**

A heart/lung transplant refers to the transplantation of one or both lungs and heart from a single cadaver donor. A combined heart/lung transplantation is intended to improve and prolong function in patients with end stage cardiopulmonary or pulmonary disease. This involves procurement of the donor heart/lung, excision of recipient heart-lung, and implantation to recipient.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

### **2.2 Special Provisions**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

### 3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

The N.C. Medicaid program covers heart/lung transplantation for patients with end-stage heart-lung disease of any etiology who meet the following criteria: (not all inclusive)

1. irreversible primary pulmonary hypertension with heart failure
2. chronic obstructive pulmonary disease with heart failure
3. non-specific severe pulmonary fibrosis
4. Eisenmenger's complex with irreversible pulmonary hypertension and heart failure
5. cystic fibrosis with severe heart failure
6. emphysema with severe heart failure
7. severe coronary artery disease or cardiomyopathy with irreversible pulmonary hypertension
8. non-complex congenital heart disease associated with pulmonary hypertension that is not amenable to lung transplantation and repair by standard cardiac surgery
9. pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure

### 4.0 When the Procedure is Not Covered

Heart/lung transplantation is not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

#### 4.1 Non-covered Conditions

The N.C. Medicaid program does not cover heart/lung transplantation when one of the following conditions exist: (not all inclusive)

1. advanced age (generally over 65)
2. malignancy involving the lung (primary, or metastatic)
3. non-pulmonary malignancy (must be five years cancer free)
4. progressive neuromuscular disease
5. clinically severe obesity
6. HIV positive
7. smoking/tobacco use – must be abstinent for a minimum of one year
8. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

**Note:** To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

9. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
10. other major organ system disease or infection including major vascular disease

11. multi-system disease (Patients with scleroderma, other collagen vascular diseases such as systemic lupus erythematosus, or sarcoidosis must be carefully evaluated to ensure disease is confined to the lung.)
12. unstable cerebrovascular disease
13. psychosocial history that would limit ability to comply with medical care pre- and post-transplant

#### **4.2 Donors**

Living donor expenses **are not applicable** for a heart/lung transplant.

### **5.0 Requirements for and Limitations on Coverage**

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All heart-lung transplantations must be prior approved by DMA.

### **6.0 Providers Eligible to Bill for the Procedure**

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

### **7.0 Additional Requirements**

FDA approved procedures, products, and devices for implantation must be utilized for heart/lung transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

### **8.0 Policy Implementation/Revision Information**

**Original Effective Date:** January 1, 1985

#### **Revision Information:**

<b>Date</b>	<b>Section Revised</b>	<b>Change</b>
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

## **Attachment A Claims Related Information**

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

**A. Claim Type**

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

**B. Diagnosis Codes**

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

**C. Procedure Codes**

The following code is covered for heart/lung transplantation: 33935

**D. Providers must bill their usual and customary charges.**